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| 09/982,091      | 10/17/2001  | Akiko Kumagai        | CIT1320-1           | 6755             |

7590 04/28/2004

Lisa A. Haile, J.D., Ph.D.  
GRAY CARY WARE & FREIDENRICH LLP  
Suite 1100  
4365 Executive Drive  
San Diego, CA 92121-2123

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| EXAMINER |
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SULLIVAN, DANIEL M

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| ART UNIT | PAPER NUMBER |
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1636

DATE MAILED: 04/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

34.

## Office Action Summary

### Application No.

09/982,091

### Applicant(s)

KUMAGAI ET AL.

### Examiner

Daniel M Sullivan

### Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 6 and 16-22 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5 and 10 is/are allowed.
- 6) ☒ Claim(s) 7-9 and 11-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This Non-Final Office Action is a reply to the "Amendment in Response..." of 15 January 2004, filed in response to the Non-Final Office Action mailed 12 August 2003. Claims 1-4, 6 and 16-22 were withdrawn from consideration and claims 5, 7 and 8-15 were considered in the 12 August Office Action. Claims 5, 8-10 and 12 were amended in the 15 January Paper. Claims 1-22 are pending and claims 5, 7 and 8-15 are under consideration.

#### ***Priority***

In the previous Office Action, claims directed to SEQ ID NO: 3 and 5 (i.e., the human nucleic acid sequences) were denied benefit of US Provisional application 60/241,246 because the sequences were not disclosed therein. In reply, Applicant contends that the priority application discloses the nucleic acid sequence set forth in the instant application by reference to GenBank accession number AF297866. This argument has been fully considered but is not deemed persuasive because the citation of AF297866 is not a proper incorporation by reference. The MPEP states, "Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973)." (608.01(p)(I)). Therefore, the subject matter disclosed in AF297866 cannot be relied upon as descriptive support for the present SEQ ID NO: 3.

Applicant further argues that SEQ ID NO: 5 should also be afforded benefit of the provisional application because SEQ ID NO: 5 is closely homologous with SEQ ID NO: 3. This

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argument is not deemed persuasive at least because SEQ ID NO: 3 is not supported by the provisional application (*Id.*).

Applicant's arguments have been fully considered but are not deemed persuasive.

Therefore, claims 5, 8 and 11-15 will be afforded an effective filing date of 17 October 2000, and claims 7, 9 and 10 will be afforded an effective filing date of 17 October 2001.

### ***Response to Amendment***

#### **Claim Rejections - 35 USC § 112**

Rejection of claims 5, 9 and 10 under 35 U.S.C. §112, first paragraph, as lacking adequate written description is withdrawn in view of the amendments to the claims.

Claim 8 and 11-15 stand rejected under 35 U.S.C. §112, first paragraph, as lacking adequate written description for reasons of record and herein below in the response to arguments.

Rejection of claims 9 and 10 under 35 U.S.C. §112, first paragraph, as lacking enablement for the full scope of the claimed subject matter is withdrawn in view of the amendments to the claims.

Claims 8 and 11-15 stand rejected under 35 U.S.C. §112, first paragraph, as lacking enablement for the full scope of the claimed subject matter for reasons of record and herein below in the response to arguments.

Rejection of claims 12 and 13 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of the amendments to the claims.

Claim Rejections - 35 USC § 102

Rejection of claims 8-10 under 35 U.S.C. 102(a) as being anticipated by Accession No. AL354864 is withdrawn. Claim 8 has been amended such that it is now afforded the effective filing date of 17 October 2000. Therefore, claim 8 and claims 11-15, which depend from claim 8, are no longer anticipated by the art. Claims 9 and 10 have been amended such that they are now limited to sequences not disclosed in the AL354864 publication.

Rejection of claims 8-10 under 35 U.S.C. 102(b) as being anticipated by either one of Accession No. AP001261 (31 May 2000) or Accession No. G30470 (1996) is withdrawn. Claim 8 has been amended such that it is no longer directed to a nucleic acid that hybridizes to SEQ ID NO: 3, and claims 9 and 10 are now limited to sequences that are not disclosed in the AP001261 and G30470 publications.

***Response to Arguments***

Claim Rejections - 35 USC § 112

Claims 8 and 11-15 were rejected under 35 U.S.C. §112, first paragraph, as lacking written description for any nucleic acid comprising at least 15 continuous bases and that hybridizes to a polynucleotide encoding a polypeptide having an amino acid sequence as set forth in SEQ ID NO: 2 or 4 or to a polynucleotide having a sequence set forth as SEQ ID NO: 1.

In response to the *prima facie* case, Applicant has amended claim 8 to recite that nucleic acid has “at least 15 continuous bases and that specifically hybridizes under highly stringent

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conditions...” Applicant urges that hybridization of the polynucleotide fragment is dependent upon the presence of a polynucleotide encoding SEQ ID NO: 2 or SEQ ID NO: 4; a nucleotide sequence as set forth in SEQ ID NO: 1 or variants specified in the claim. Applicant argues that the specification provides ample support for polynucleotides “having” the disclosed sequences and therefore the claims are entitled to broader scope than the exact sequences set forth in the sequence listing.

These arguments have been fully considered but are not deemed persuasive. It would seem that Applicant has misunderstood the Examiner’s position, which is not that the sequence encompassed by the claim should be limited to the exact sequence set forth in the sequence listing. The claim is constructed such that the metes and bounds of the claimed sequence are defined by their ability to hybridize with the polynucleotides defined in parts (a)-(e). In other words, the polynucleotides of (a)-(e) are reference sequences from which the claimed sequence might differ within the constraints of the hybridization conditions. Therefore, if the reference sequences contain undefined sequence or differ significantly from the sequences disclosed in the specification, the claims are construed to encompass sequence that has little or no structural similarity to the disclosed sequence. Thus, the claims lack descriptive support.

With regard to limitation of the hybridization conditions to “highly stringent”, the specification does not set forth a limiting definition of “highly stringent” conditions (the conditions set forth in paragraph [0044] are indicated as exemplary) such that nucleic acids having low structural similarity to the disclosed nucleic acids would be excluded from the claimed subject matter. Therefore, claims limited to “highly stringent” conditions are construed,

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according to their broadest reasonable interpretation, to encompass nucleic acids having low homology with the disclosed nucleic acids.

Applicant's arguments have been fully considered but are not deemed persuasive either individually or as a whole; therefore, the claims stand rejected as containing subject matter that is not adequately described in the disclosure.

Claims 8 and 11-15 were rejected under 35 U.S.C. 112, first paragraph, as lacking enablement for all polynucleotides comprising 15 continuous bases that hybridize with some undisclosed sequence; any polynucleotide that comprises 15 continuous bases that hybridize to one of the disclosed sequences; or fragments of undisclosed sequence.

In response to the *prima facie* case, Applicant points out that claim 8 has been amended to clarify that the polynucleotide fragment useful in the claimed methods “specifically hybridizes under highly stringent conditions”. This argument has been fully considered but is not deemed persuasive because, for the reasons set forth above, the subject matter encompassed by the amended claims is still beyond the scope of what the skilled artisan would know how to use. Therefore, the claims stand rejected under 35 U.S.C. §112, first paragraph, as lacking enablement for the full scope of the claims.

#### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 8 and 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Goodearl *et al.* (June 1999) WO 99/28470.

Goodearl *et al.* describes an isolated nucleic acid molecule that is at least 15 contiguous nucleotides in length and hybridizes under stringent conditions to a nucleic acid molecule comprising the sequence set forth by Goodearl *et al.* as SEQ ID NO: 4 (see especially the first full paragraph on page 8). As nucleotides 2164 to 2203 of SEQ ID NO: 4 are identical to nucleotides 4715 to 4754 of the instant SEQ ID NO: 1, the nucleic acid molecule of Goodearl *et al.* is the same as the nucleic acid molecule of claim 8. Goodearl *et al.* further teaches recombinant expression vectors containing the nucleic acid molecules and host cells comprising said expression vectors according to the limitations of claims 11 and 14 (see especially the second full paragraph on page 8); teaches that the expression vectors can be a plasmid or a viral vector according to claims 12 and 13; and teaches a method for producing a polypeptide using the disclosed host cell (see, *e.g.*, the first full paragraph on page 8), which the skilled artisan would understand to comprise the steps set forth in claim 15.

The nucleic acid, host cell, vector and method taught by Goodearl *et al.* are the same as those claimed in the instant application; therefore, the claims are anticipated by Goodearl *et al.*



Claims 7 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Schlegel *et al.* (International filing date: 20 February 2001) WO 01/60860.

Schlegel *et al.* discloses a nucleic acid comprising a sequence that is identical to nucleotides 1-4727 of the instant SEQ ID NO: 3 (see the attached sequence alignment) and encodes the instant SEQ ID NO: 4. Thus, to the extent that they are directed to a polynucleotide encoding SEQ ID NO: 4, claims 7 and 9 are anticipated by the nucleic acid disclosed by Schlegel *et al.*

PLEASE NOTE: This rejection was not applied to claims 5, 8 or 11-15 because it was not possible to determine which of the Provisional applications relied upon by the Schlegel *et al.* publication for priority disclose the sequence encoding the instant SEQ ID NO: 4. Applicant is advised that if the nucleic acid is disclosed in any one of 60/183,319, 60/189,862, 60/207,454, 60/211,314, or 60/219,007, the 102(e) date of the Schlegel *et al.* disclosure antedates the effective filing date of the instant claims 5, 8 and 11-15 and the claims would be anticipated by Schlegel *et al.*

#### ***Allowable Subject Matter***

Claims 5 and 10 are allowed.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779.


The examiner can normally be reached on Monday through Thursday 6:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DMS

  
DAVID GUZO  
PRIMARY EXAMINER